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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,244	12/06/2001	Robert Sixto JR.	SYN-064 A	5798

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EXAMINER

PANTUCK, BRADFORD C

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/010,244

Applicant(s)

SIXTO ET AL.

Examiner

Bradford C Pantuck

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 13-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) ~~1-12~~ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/6/2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-18, drawn to a method of clipping body tissue, classified in class 606, subclass 153.
- II. Claim 19-25, drawn to a method of using an endoscope to do perform a surgical procedure, classified in class 606, subclass 142.

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Invention I does not claim using an endoscope, whereas Invention II claims an endoscope and many particulars relating to that endoscope.

This application contains claims directed to the following patentably distinct species of the claimed invention:

Species 1: method of applying a clip with connected arms (Claims 1-12)

Species 2: method of applying a clip with unconnected arms (Claims 13-18)

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Greg Maybeck on 8/6/03 a provisional election was made with traverse to prosecute the invention of Invention I, Species 1 "method of applying a clip with connected arms", claims 1-

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12. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13-25 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o).
Correction of the following is required: Claim 1 (and subsequent claims) line 2 purports that the clip slides over body tissue. The Applicant does not show a picture of this or describe this process in the Specification. The word "slide" appears nowhere in the Specification.

Claim Objections

2. Claim 5 is objected to because of the following informalities: in line 3 of Claim 5 the phrase "from a first portion" is spelled incorrectly. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 7 recites the limitation "said fundus" in line 3. There is insufficient antecedent basis for this limitation in the claim.
4. Claims 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what the Applicant means by the phrase "single clip applier." Does the Applicant mean to claim that there is only one [single] machine used to carry out the procedure, or does the Applicant mean to claim that the machine is only capable of applying one [single] clip?

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 5, 6, and 9-11 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 5,037,021 to Mills et al. Regarding Claims 1, 2, 5, and 6, Mills' method includes grasping the region of tissue from an interior surface of the stomach, and configuring the region of tissue to create at least one fold of tissue. As described in Column 6, lines 14-41, the clip (209) inserted by Mills' clip applier (200) manipulates the tissue (216) into a fold and holds the invaginated section after being

inserted. The clip is locked in place [Column 6, lines 31-33] and will not let the stomach resume its pre-folded condition, because of the way that the staple *pierces* and encompasses the fold of tissue [see Figures 5a-5c].

The clip has two arms and a bridge coupling the two arms, as shown in Attachment #1. The clip (209) slides over the body tissue (216) when the body tissue is sucked into the chamber (and into the clip), as shown in Figure 5a, and described in Column 6, lines 20-22. As the tissue is sucked into the clip, it will *contact* Arm A [as shown in Fig. 5a], and presumably the clip and the tissue will *slide relative to each other*. As shown in Figure 5C, body tissue is located between the two arms. The clip applies a compressive force to the body tissue [Column 6, lines 30-34]. The clip applier bends both of the arms, and one of them is bent through the whole thickness of the *both portions of tissue* [see progression from Figure 5a to 5c]. In Column 6, lines 22-28, Mills says that the remaining sections of the clip [i.e. Arm A and the bridge] are *deformed* (synonym for *bent*) during the application of the clip to the body tissue. Figure 5c shows Arm B being bent through the thickness of the body tissue. Thus both arms are bent during the application of the clip.

Mills discloses that his invention is intended to be used for “the attachment of materials or objects” to the *interior of the stomach* [Column 1, lines 44-45, 47-49].

6. Regarding Claim 9, Mills discloses compressing and clamping first and second portions of tissue (216) into contact with each other [see Fig. 5a] prior to sliding the clip and tissue sliding relative to each other. In Column 6, lines 9-10 Mills explains that prior to use the cavity is preloaded with the clip. Using logic, before the tissue

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can fit through the opening in the clipping device's cavity (202) it must already be in a folded condition.

7. Regarding Claims 10 and 11, as best understood, the sliding and the bending are accomplished by using a single clip applier. Column 6, lines 33-37 explains that the clip applier may contain a single clip or multiple clips. Further, only one [single] machine is used to carry out this process.
8. Claims 1, 3, and 4 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 5,571,116 to Bolanos et al. Regarding Claims 1 and 4, Bolanos discloses a method of sliding a clip over body tissue. The clip (30) has two arms and a bridge coupling the arms, as shown in Figure 31. The arms are the parallel parts and the bridge is the perpendicular portion connecting the arms. Body tissue is located between the two arms, such that the clip applies force to the body tissue. Each clip is bent through the entire thickness of the body tissue [see progression from Figure 30 to Figure 31].
9. Regarding Claim 3, Bolanos discloses a method of bending each arm into contact with each other. As can be seen in Figures 5B and 31, the arms are bent into contact with each other.
10. Claims 1 and 12 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 5,582,611 to Tsuruta et al. The clip (22) has two arms and a bridge coupling the arms, as shown in Figure 61. The arms are the parallel parts and the bridge is the perpendicular portion connecting the arms [see Figures 42 and 43].

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Body tissue is located between the two arms, such that the clip applies force to the body tissue. Each clip is bent through the entire thickness of the body tissue [see progression from Figure 42B to Figure 42C].

11. Regarding Claim 12, the clip connects two separate pieces of tissue. "Tissue a" is connected to "tissue b." There is a gap between the two tissues, therefore they are considered to be separate, i.e. disunited or withdrawn from each other [Fig. 42A; Column 18, lines 5-10].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,037,021 to Mills et al. in view of U.S. Patent No. 5,571,116 to Bolanos et al.

12. Regarding Claim 7, Mills discloses manipulating the region of tissue to create at least two adjacent folds of tissue [Column 6, lines 30-38]. Assumedly, one embodiment of Mills' device contains at least two staples so that they can be applied to folds of tissue close to the location of the first clip.
13. Regarding Claim 8, Mills discloses grabbing the interior of the stomach with a grasping instrument and pulling on the interior of the stomach to cause invagination

of the interior of the stomach. Using suction, the tissue is *pulled* into the cavity (202) in the clip applicator [Column 6, lines 7-9; Fig. 5a]. During the clipping process, the interior of the stomach is held in the cavity of the grasping instrument *both by the vacuum and by the incidental contact between the tissue and the grasping instrument*. Further, Mills discloses holding the tissue mechanically [grabbing it], with piston 205 [see Fig. 1b].

With regards to Claims 7 and 8, Mills does not disclose that his procedure is done specifically in the part of the stomach called the *fundus*. However, Bolanos teaches that one would bend clips having two arms and a bridge completely through a fold of the fundus in the stomach *in order to help alleviate gastroesophageal reflux disease*. Mills teaches that in order to treat this disease effectively, one ought to attach the patient's lower esophagus to the patient's fundus [Column 2, lines 55-62]. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to perform the surgery disclosed by Mills to attach the lower esophagus to the fundus in order to alleviate gastroesophageal reflux disease in a patient, as taught by Bolanos.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Publication No. US 2002/0183768 to Deem et al.

U.S. Patent No. 6,506,196 to Laufer

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U.S. Patent No. 6,572,629 to Kalloo et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on (703) 308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

BCP
BCP

August 8, 2003


MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
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